REMARKS

Applicants thank the Examiner for withdrawing the rejection based on 35 U.S.C. § 102. However, the Examiner further rejected the claims of the instant application as obvious in view of Sonne. Reconsideration of the instant application is respectfully requested in view of the following remarks. No amendments have been made with this response. Accordingly, the instant response does not introduce any new matter.

The claims of the instant application are drawn, in one aspect, to a composition suitable for administering a therapeutic dose of a corticosteroid to the respiratory tract, consisting of: (a) from about 5 μg/ml to about 5 mg/ml of a corticosteroid in dissolved form, (b) from about 0.1 to about 20 percent by weight of a pharmaceutically acceptable, high-HLB surfactant component, wherein the HLB of the surfactants present in the high-HLB surfactant component is greater than about 10, and wherein the high-HLB surfactant component comprises at least 50% by weight of an ethoxylated derivative of vitamin E; and (c) at least about 70 weight percent aqueous phase.

A. Rejection based on 35 U.S.C. § 103

The Examiner further rejected the claims of the instant application as obvious in view of Sonne. Specifically, the Examiner argues that the difference between Sonne and the instant invention is within routine experimentation and optimization.

The gist of the Examiner's argument comes down to the assertion that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the composition by substituting the alpha tocopherol of Example 15 with a vitamin e-TPGS..." Office Action at 4. Applicants respectfully traverse.

While the Examiner is arguing that Sonne discloses addition of various oils, alcohol, and other co-solvents, the issue is whether the disclosure of Sonne would lead one of skill in the art to the removal of the most crucial element of his composition, namely, α-tocopherol. Applicants respectfully submit that Sonne does not provide any motivation to remove α-tocopherol from his compositions and replace it with Vitamin E TPGS.

According to Sonne, α-tocopherol and Vitamin E TPGS are used for different purposes. Alpha-tocopherol is used as a solvent of the active ingredient, whereas

Vitamin E TPGS is used as an emulsifier. While Sonne disclosed that α-tocopherol or a derivative thereof may be used as a solvent, Sonne never considered the possibility of using Vitamin E TPGS for that purpose.

While the Examiner quotes from Sonne extensively, the fact remains that vitamin E TPGS is never mentioned in Sonne as a solvent, nor is it suggested as a solvent. In fact, Sonne implicitly excludes Vitamin E TPGS from the list of suitable solvents. See, e.g., Col 4, lns 40-44 ("Stable emulsions may readily be achieved according to the invention using a range of tocopherols or derivative compounds as solvents, with Vitamin E TPGS as emulsifier.") *Emphasis added.* See also Col 5, ln 65 – Col. 6 ln 2 ("The active ingredient can be dissolved in the lipid fraction of the tocopherol solvent and other solvents may be added if desired. The emulsifier, e.g., Vitamin E TPGS, and optionally other emulsifiers, can be added to either the old and/or the water phase." *Emphasis added.*) Even the quotation used by the Examiner on page 4 of the Office Action indicates that "tocopherol derivatives, particularly certain esters, may themselves form efficient, non-irritating emulsifiers to enable stable emulsions to be formed." *Emphasis added.* Also see page 5 of the Office Action, where the Examiner interprets Sonne as follows: "the tocopherol derivative emulsifier of the invention may be used alone or in conjunction with other known emulsifiers…" Thus, Sonne all but explicitly excludes the possibility that Vitamin E TPGS may be used as a solvent.

While the Examiner concludes that there is "a reasonable expectation of successfully producing a composition that is non-irritating with optimized bioadhesion, sprayability, viscosity, without compromising the stability of the emulsion," this is not the issue at hand. Even assuming, but without agreeing, that the composition may be produced, the issue is not whether this composition may be produced, but how it may be produced. Sonne does not suggest that such a composition may be produced by removing the most important ingredient of his composition, namely, α-tocopherol. Nowhere in the reference it is taught or suggested that the removal of this crucial ingredient would be expected to result in a combination that is useful for any purpose.

Further, with regard to the term "optimize," the Examiner does not provide any support that removal of the most crucial ingredient of Sonne would, in fact, optimize, the composition or even provide composition having identical or similar chemical and/or

pharmacokinetic properties. Without this support, the Examiner engages in speculation and hindsight reasoning for the motivation to remove α-tocopherol. In view of the portions of Sonne quoted above, one of skill in the art would not be motivated to exclude α-tocopherol from the compositions of Sonne in order to arrive at the instant invention. Simply put, it is unlikely that one of skill in the art would not have guessed that the composition would be "optimized" after removal of its most crucial ingredient.

Second, Applicants further respectfully note that the compositions of the instant invention retain the useful functions of Sonne's composition, and yet they disclose fewer elements than Sonne's composition, including embodiments with possible omission of an element, namely, α-tocopherol, which, according to Sonne, is crucial. Accordingly, removal of an element which prior art implies is crucial is not a routine experimentation. It is a well-settled law that an "omission of an element and retention of its function is an indicial of unobviousness. *In re Edge*, 359 F2d 892, 149 USPQ 556 (CCPA 1966)." MPEP § 2144.04.II.B.

Applicants further submit to the Examiner's attention to *In re Geiger*, 815 F2d 686, 688 (Fed. Cir. 1987), where the Court held that "[o]bviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination." In *Geiger*, the "teaching suggestion or incentive" was absent and the references were merely silent regarding the combination claimed in *Geiger*, and yet the Court found that the prior art references were insufficient for the *prima facie* case of obviousness.

In this case, Sonne is all but explicitly states that Vitamin E TPGS should be used as an emulsifier, rather than a solvent (the solvent being α-tocopherol), thereby suggesting that α-tocopherol must be present in the composition, which is directly opposite to the instant claims. Accordingly, following the logic of *Geiger*, the Examiner has not shown the prima facie case of obviousness of the instant claims in view of Sonne.

Therefore, for the aforementioned reasons, Applicants respectfully request the Examiner to withdraw the instant ground for the rejection.

B. Double Patenting Rejection

The Examiner has also rejected the claims of the instant application under the doctrine of non-statutory obviousness-type double patenting as being obvious over the claims of U.S. Patent No. 6,241,969. Applicants respectfully request the Examiner to hold this rejection in abeyance until all other rejection grounds have been overcome.

CONCLUSION

In view of these amendments and remarks, Applicants believe that the claims of this application are in condition for allowance and an early notice to this effect is earnestly solicited. If the Examiner does not believe that such action can be taken at this time or if the Examiner feels that a telephone interview is necessary or desirable, Applicants welcome the Examiner to call the undersigned at 609-844-3021.

The USPTO is authorized to charge Deposit Account No. 50-1943 for any charges in connection with this matter.

Respectfully submitted,

Date: January 27, 2009

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